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| 10/796,882 | 03/08/2004 | David Radunsky | 067062.0127 | 2882 |

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| EXAMINER | |
|---|---|
| DRODGE, JOSEPH W | |

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| 1723 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/796,882 | RADUNSKY ET AL. | |
| | Examiner | Art Unit | |
| | Joseph W. Drodge | 1723 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *6,8-11 and 17-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,8-11 and 17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *062007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kotitschke patent 4,900,720.

For independent claim 6, Kotitschke discloses a pharmaceutical grade solution (see plasma exchange medium beginning at Abstract and text beginning at column 3, line 52 concerning the formulation being in solution) that is formulated to treat many toxic diseases [as with instant claims 5 and 10] (column 1 lines 37-45, etc.), and contains albumin (up to 35-50 g/l or more), inflammatory mediators (igG, igA) and other receptor molecules (column 3, lines 35-52). The albumin and other constituents in the replacement fluid medium are rendered sterilized or "clean", as claimed, by ultrafiltration, exposure to a propriolactone sterilizing substance and exposure to ultraviolet (UV) radiation (column 3, lines 45-51 and several sections of text of column 6, lines 32-66). The albumin and other constitutents also have binding sites operable to attract inflammatory mediators from tissue of the patient. The disclosed solution also contains a balanced amount of salts and other electrolytes (column 6, lines 60-64 and

Table concerning "Electrolytes" on column 7). The plasma containing the albumin and other receptor molecules is considered the claimed "carrier medium".

On further evaluation and review, recitation of the fluid as being for replacement of fluid and constituents having been removed from blood during hemofiltration, as well as characteristics of the hemofiltration are not considered as limiting the claimed composition. Such recitations are now considered as merely describing intended use and purpose of the composition. Any filtration that occurs to fluid from a patient is materially unrelated to and independent of preparation of or constituents of the plasma replacement fluid itself, that may optionally be used in treatment of such patient.

Recitations of characteristics of a filter optionally employed with use of the fluid also have little patentable weight, since they do not limit any parameter or characterstic of fluid composition.

For claims 8 and 9, the concentration of albumin may fall within the claimed concentration range of between about 0.5 g/100 ml (5g/l) to 20 g/ml (200g/l), (see Kotitschke at column 3, line 38, and Tables at columns 7 & 8 and also Hoffman at column 21, line 14).

For claim 10, Kotitschke includes replacement receptor and inflammatory mediator molecules (see column 3, lines 29-47 concerning igG, igA, igM and macroglobulin).

Claims 17-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Roberts et al patent 5,944,684, supplied with the 6/07 IDS.

Roberts discloses blood flow circuit for flowing and treating a portion of removed blood that includes metabolites, waste metabolites, plasma substances including albumin and associated immunoglobulins and proteins and other cellular debris (column 5, lines 45-55 and column 6, lines 25-43). The circuit is including tubing/ultrafiltrate tubing 2 and 3 and other conduits shown in figure 2,, the circuit having one or more "large pore/very large pore" ***hemofilters*** 10, operable to sieve large molecules including some of albmumin and immunoglobulins while allowing passage of smaller molecules (column 5, line 62-column 6, line 11 and column 6, lines 24-40) selected from among membranes having a wide range or porosities or molecular size cutoffs, producing a filtered stream that passes through protein purifier 13 and then to reservoir 14 and an ultrafiltered stream that passes through ultrafiltrate purifier 11 en route also to the reservoir. The term "hemo" in "hemofilter" is synonymous with blood. The hemofilter of Roberts inherently has a molecular weight cutoff of larger than 150, 000 Daltons since it

is sized to retain some of the blood proteins, albumin and immunoglobulins , while allowing other proteins to pass through in the stream of filtered blood to protein purifier 13 (see figures, column 6, lines 1-12 and 24-56).

With regard to claims 18 and 19, relative amounts of albumin or any other substance in the replacement fluid carry little patentable weight, since no structural feature is recited in these claims.

For claims 20-22, the blood filter inherently has a nominal molecular weight cutoff of a value smaller than millions of Daltons, since some proteins are retained/ i.e. remain in the ultrafiltrate stream , rather than the filtered stream.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kotitschke patent 4,900,720 in view of Antwiler patent 4,968,432.

Claim 11 differs from Kotitschke in requiring the fluid to be contained in a reservoir having at least one port operable to communicate the fluid from the reservoir.

Antwiler teaches source or reservoir having plasma colloid replacement fluid 64, coupling/port to flow lines 66,68,71 to connect flow of the fluid with an extracorporeal blood plasma purification circuit 29,56,20. It would have been obvious to one of ordinary skill in the art to have utilized the fluid of Kotitschke et al in a kit having a reservoir and outlet port, as taught by Antwiler, in order to enable storing of adequate amounts of fluid to maintain the health and safety of the patient during surgical and other medical procedures when relatively large amounts of replacement fluid are required to replace fluid and components lost during the procedures.

Applicant's arguments filed on June 13, 2007 concerning claims 6-11 have been fully considered but they are not persuasive.

With respect to claims 1,3-6 and 8-10, it is argued that Kotitschke has a composition appropriate for use with a plasmapheresis system rather than with a conventional extracorporeal blood circuit. However, since these are composition claims, the type of filtration system with which the composition is utilized is immaterial.

It is further argued that since Kotitschke utilizes a composition that contains immunoglobulins, as essential, it cannot be combined with any reference that discloses removal of immunoglobulins. It is submitted that the instant claims neither preclude presence of immunoglobulins or their absence in the claimed fluid composition.

With respect to claim 11, it is argued that Antiwiler does not disclose any fluid "kit". It is submitted that although the terminology "kit" is not specifically denoted by the reference, the commonly understood meaning of "kit" is any assembled set of parts or materials. The system of Antwiler contains a plurality of parts and materials.

It is argued that the replacement fluid of Kotitschke et al is for different functions than that of applicant's pertaining to "rapid restoration of a protein profile" and more permanent patient infusion rather than the specific goal of removal of toxins and not administered with the purpose of later removal of molecules loaded with toxins during the same treatment. Additional differences in purpose and function are pointed out including removal of red or white blood cells from a patient, and relative amount of blood coagulation factors present While none of such differences in purpose or function are disputed, it is submitted that the argued claims are composition claims, rather than method, process, or system claims, hence are independent of medical or surgical procedures concerning any patient that may be a recipient of such composition.

It is argued that in Kotitschke et al, plasmapheresis is conducted which is a radically different method than a treatment process that does not remove significant amounts of immunolglobulins and other large molecules, Again, the manner of treating fluids from a patient are quite independent of ingredients of any composition that may be used in the treatment of any patient regardless of whether or how such patient's blood or plasma has been treated or will be treated after receiving the plasma replacement composition.

Applicant's arguments with respect to claims 17-22 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment, and also information accompanying the Information Disclosure Statement submitted on June 13, 2007, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Roy Sample, can reached at 571-272-1376. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

July 17, 2007

JOSEPH DRODGE
PRIMARY EXAMINER